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10/580,070	05/19/2006	Toru Shimizu	053673-0030	9492

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MCDERMOTT WILL & EMERY LLP  
600 13TH STREET, N.W.  
WASHINGTON, DC 20005-3096

EXAMINER
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MOORE, WALTER A

ART UNIT	PAPER NUMBER
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1789

NOTIFICATION DATE	DELIVERY MODE
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06/23/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/580,070	<b>Applicant(s)</b> SHIMIZU ET AL.	
	<b>Examiner</b> WALTER MOORE	<b>Art Unit</b> 1789	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6,8,11-14,16-20 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,8,11-14,16-20 and 23-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **RESPONSE TO AMENDMENT**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/9/2011 has been entered.

### ***Status of Claims***

2. Claims 1, 3, 5-6, 8, 11-14, 16-20, and 23-28 are pending. In the response filed on 6/9/2011, claims 25-28 were added.
3. Claims 2, 4, 7, 9-10, 15, and 21-22 were previously canceled.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3, 5-6, 8, 13-14, 17-20, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida et al., USPN 6,570,010, in view of Ishida et al., WO

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2003/074622. The rejection refers to Ishida et al., USPA 2005/0129721, which is being used as the English language equivalent of Ishida et al., WO 2003/074622 (cited in the IDS filed on 5/19/2006).

Regarding claims 1, 6, 8, 13-14, 17-20, and 27: Ishida '010 discloses a beverage (carbonated beverage, col. 9, ln. 36) comprising a concentrated fruit juice component (lemon juice concentrate, col. 9, ln. 46), a base with sweetness (liquid sugar dextrose, col. 9, ln. 47), and a flavor improving substance (vanillyl-n-butyl ether, col. 9, ln. 49).

Ishida '010 suggests the flavor improving substance (vanillyl-n-butyl ether) can be mixed with food and drink beverages (col. 4, ln. 66) that include cool-feeling substances (col. 4, ln. 56) and refreshing feeling substances (col. 4, ln. 61). Ishida '010 suggests cool- and refreshing feeling substances including: menthol, 3-(1-menthoxy)propane-1,2-diol, 3-(1-menthoxy)-2-methylpropane-1,2-diol (col. 4, ln. 57-60). Ishida '010 discloses the combination improves the duration and cool-feeling or refresh-feeling imparting effect (col. 4, ln. 60-62).

However, Ishida '010 does not expressly disclose the beverage includes a combination of cool-feeling substances and refreshing feeling substances (presently claimed as menthol).

Ishida '721 is drawn to cool feeling compositions having a high cooling effect (p. 1, para 0001). Ishida '721 discloses it is known in the art to combine two or more cool feeling substances to enhance cooling effect (p. 1, para 0005). Ishida '721 discloses the composition is useful in food and drink compositions (p. 1, para 0011). Ishida '721

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discloses the composition includes menthol combined with 3-1-menthoxypropane-1,2-diol (p. 2, para 0019).

It would have been obvious to one of ordinary skill in the art at the time of invention to add menthol and cool-feeling substances, as taught in Ishida '721, to the beverage composition, taught in Ishida '010, to obtain a beverage composition comprising menthol and cool feeling substances. One of ordinary skill in the art would have been motivated to use a combination of menthol and cool feeling substances because they a cooling effect having excellent persistency in food and drink compositions (p. 1, para 0010).

Regarding the amount of the menthol and cool-feeling substance, Ishida '721 discloses a food and drink composition comprises between 0.001% and 20% by weight of the total cool feeling composition (p. 2, para 0025). Ishida '721 discloses the composition includes components (A), (B), and (C) (p. 2, para 0019). Ishida '721 discloses component (A) is menthol (p. 2, para 0019). Ishida '721 discloses component (B) is at least one compound selected from 3-(1-menthoxy)propane-1,2-diol and 2-(1-menthoxy)ethane-1-ol (p. 2, para 0019).

Ishida '721 discloses the composition ratios of the above ingredient (A) to the ingredient (B), the ingredient (B) to the salicylic acid ester (C), and the ingredient (A) to the above ingredient (C) by weight are 95:5 to 30:70, 90:10 to 30:70, and 99.5:0.5 to 30:70, respectively (p. 2, para 0020).

As a single example of an overlapping range, Ishida '721 discloses an overlapping range of menthol and cool feeling substances (3-(1-menthoxy)propane-1,2-

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diol and 2-(1-menthoxy)ethane-1-ol). The present claims recite menthol is between 0.009 to 0.045 parts per 1000 of the product. The converts to between 0.0009% and 0.0045%. ( $0.009/1000 * 100\% = 0.0009\%$ ). The present claims recite the cool feeling substance is between 0.001 to 0.005 parts to 1000 parts product. The converts to between 0.0001% and 0.0005%.

Taking the ratio provided by Ishida '721 one can calculate a range of menthol and cool feeling substance between 0.00023% and 4.6%. Sample calculation: (C) represents 70 parts of the composition. Then (A) equals 30 parts and (B) equal 30 parts. Therefore, (A) and (B) represent about 23% of the composition ( $\{30 \text{ parts} / [30 + 30 + 70]\} * 100\% = 23\%$ ). Therefore, the amount of (A) and (B) can each be 23% of the total 0.001% to 20% range of the Ishida '721 composition in a food product (Ishida '721, p. 2, para 0025).  $23\% \text{ of } 0.001\% = 0.00023\%$  and  $23\% \text{ of } 20\% = 4.6\%$ .

The examiner notes that this is a single example calculation. Various combinations of the ratios suggested in Ishida '721 result in ranges that overlap the presently claimed ranges. In the case where the claimed ranges overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. MPEP 2144.05 I.

Furthermore, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or

workable ranges by routine experimentation. MPEP 2144.05 II. In the present case, the prior art suggests overlapping ranges of menthol and cool feeling substances.

Regarding claim 3, Ishida '010 discloses the base with sweetness is dextrose (liquid sugar dextrose, col. 9, ln. 47), which is another name for glucose.

Regarding claim 5, Ishida '721 discloses the ratio of a refreshing feeling substance (component (A) menthol) to a cool feeling substance (component (B) 3-1-menthoxypropane-1,2-diol), is between 95:5 to 30:70 (p. 2, para 0020). The inverse of which converts to 5:95 to 70:30 parts cool feeling substance (component (B) 3-1-menthoxypropane-1,2-diol) per refreshing feeling substance (component (A) menthol). This converts to between 0.0526 to 0.428 parts cool feeling substance per 1 part refreshing feeling substance (menthol). Ishida '721 also discloses the ratio can be 0:100 to 20:80 (component (A) to component (B), p. 2, para 0023). The inverse of which converts to 100:0 to 80:20 parts cool feeling substance (component (B) 3-1-menthoxypropane-1,2-diol) per refreshing feeling substance (component (A) menthol). Furthermore, Ishida '721 prepared an example having 0.057 parts of cool feeling to one part refreshing feeling substances (2 parts 3-1-menthoxypropane-1,2-diol to 35 parts 1-menthol, p. 10, Table 1, Example 1).

Regarding claims 17-20, the phrase, "for reinforcing a flavor," is a statement of intended use or purpose. A statement with regard to intended use is not further limiting as a manipulative difference between the process claimed and the prior art. In order to patentably distinguish the claimed invention from the prior art, a claimed intended use must result in a manipulative difference between the claimed invention and the prior art.

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See MPEP § 2111.02 II. In the present case there is no manipulative difference from the beverage, taught in Ishida '010 in view of Ishida '721, and the claimed process.

Regarding claim 25: As discussed above, the ratio provided by Ishida '721 one can calculate a range of menthol and cool feeling substance between 0.00023% and 4.6% (see sample calculation above). Furthermore, Ishida '721 discloses the ratio between the menthol (Ishida '721 ingredient A) and the cool feeling substance (Ishida '721 ingredient B) is between 19 to 0.429 (95:5 to 30:70, p. 2, para 0020). The present claim recites an amount of menthol between 0.027/1000parts to 0.045/1000 parts (claim 25, ln. 2) and cool feeling substance between 0.003/1000 parts to 0.005/1000 parts (claim 25, ln. 3-4). This represents a ratio between 5.4:1 to 15:1. Therefore, Ishida '721 discloses the ratio of menthol to cool feeling that is within the present claims.

Furthermore, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. MPEP 2144.05 II. In the present case, the prior art suggests using the presently claimed compounds for their presently claimed use. Additionally, the prior art suggests overlapping ranges of menthol and cool feeling substances.

Regarding claim 26: Ishida '721 discloses the cool feeling substance is 3-1-menthoxypropane-1,2-diol (p. 2, para 0019).



Regarding claim 28: Ishida '010 discloses lemon juice (col. 9, ln. 46). Ishida '721 discloses the cool feeling substance is 3-1-menthoxypropane-1,2-diol (p. 2, para 0019).

6. Claims 11-12, 16, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida et al., USPN 6,570,010, in view in view of Ishida et al., WO 2003/074622, as applied to claims 1, 3, 5-6, 8, 13-14, 17-20, and 25-28 above, and further in view of Kaplan, USPA 2002/0182296. The rejection refers to Ishida et al., USPA 2005/0129721 as the English language equivalent of Ishida et al., WO 2003/074622.

Ishida '010 in view of Ishida '721 is relied on as above. Ishida '010 in view of Ishida '721 does not disclose the beverage is a fruit juice containing dairy product.

Kaplan is drawn to carbonated milk beverages (p. 1, para 0002). Kaplan discloses the milk beverage can contain a fruit juice (p. 1, para 0002). Kaplan discloses carbonated milk products would be perceived as more healthy alternatives to soft drinks (p. 1, para 0006). It would have been obvious to one of ordinary skill in the art at the time of invention to include a milk product, as taught in Kaplan, in the fruit juice containing beverage, taught in Ishida '010 in view of Ishida '721, to obtain a fruit juice beverage containing milk. One of ordinary skill in the art would have been motivated to include milk because it is viewed as a healthy alternative to soft drinks (p. 1, para 0006).

Regarding claim 16, Ishida '010 discloses an additional flavor improving substance (vanillyl-n-butyl ether, col. 9, ln. 49).

Regarding claims 23 and 24, the phrase, “for reinforcing a flavor,” is a statement of intended use or purpose. A statement with regard to intended use is not further limiting as a manipulative difference between the process claimed and the prior art. In order to patentably distinguish the claimed invention from the prior art, a claimed intended use must result in a manipulative difference between the claimed invention and the prior art. See MPEP § 2111.02 II. In the present case there is no manipulative difference from the beverage, taught in Ishida ‘010 in view of Ishida ‘721 and Kaplan, and the claimed process.

### ***Response to Arguments***

7. Applicant's arguments filed 6/9/2011 have been fully considered but they are not persuasive.

Applicant argues Ishida ‘010, Ishida ‘721, and/or Kaplan fail to render the presently claimed invention obvious because the cited references fail to suggest the unexpected results (Remarks, p. 11). Applicant relies on the information presented in the specification (Remarks, p. 11, last three lines). Examiner is not persuaded by this argument.

Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. MPEP 716.02. The Applicant has the burden to establish the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. MPEP 716.02(b). Evidence

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must show unexpected results. MPEP 716.02 (a) I. Unexpected results must be commensurate in scope with the claimed invention. MPEP 716.02(d).

First, per MPEP § 716.02(d), whether unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, “objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support”. In other words, the showing of unexpected results must be reviewed to determine if the results occurred over the entire claimed range. See *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). Applicants have not provided data to show that the unexpected results do in fact occur over the entire claimed range of fruit containing food product comprising fruit component, a base with sweetness, menthol, and cool feeling substances. Applicant relies on the results reported in the specification (Remarks, p. 10 and 11). However, the examples in the specification are not commensurate in scope with the claimed invention.

The examples in the specification fail to support an unexpected result with all possible fruit components. Present claims 1, 3, 5-6, 8, 11-14, 16-20, and 23-26, recite a fruit component, which means any type of fruit component. The examples disclose the following: orange juice (p. 38, Ex 1); lemon juice (p. 42, Ex 2, Table 4; p. 47, Ex %, Table 8; p. 49, Table 10, Ex 7); apple juice (p. 45, Ex 3, Table, 6); peach juice (p. 46, Ex 4, Table 7); grapefruit juice (p. 48, Ex 6, Table 9); and grape juice (p. 52, Ex 9, Table 12). Additionally, examples 3-9 report results from ranges of menthol and cool feeling substance outside the presently claimed range. New claims 27 and 28 recite juices in

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addition to orange juice. Therefore, the results in the Specification are not commensurate in scope with the presently claimed invention.

Applicant relies on the results reported in the specification for the range of menthol and cool feeling substances (Remarks, p. 12, referring to Tables 2-3, Examples 1-(4) to 1-(6); Specification, p. 39). However, examples 1-(4) to 1-(6) used only 3-l-menthoxy-1,2-propanediol as the cool feeling substance. Present claims 1, 3, 5-6, 8, 11-14, 16-20, 23-25 and 27, recite additional cool feeling substances. Furthermore, Tables 2 and 3 reports results from example 1, a beverage with orange juice. The present claims recite fruit, which is more than just orange juice. New claims 27 and 28 recite juices in addition to orange juice. Therefore, the results in the Specification are not commensurate in scope with the presently claimed invention.

Applicant argues the prior art fails to recognize unexpected combinations of light feeling in the mouth, continuation of light feeling, light aftertaste, and no heavy feeling of sweetness (Remarks, p. 12, 1<sup>st</sup> full para). Examiner is not persuaded by these arguments. Present claim 25 represents the most specification combination of menthol and cool feeling substance. This combination of flavoring was used in orange juice in examples 1-(5) and 1-(6) (specification, p. 39, Table 2). Therefore, the claim is not commensurate in scope with the present claims.

Second, Examiner notes the properties on which the Applicant relies

(i.e. p. 40: light feeling in the mouth, continuation of light feeling, and heavy feeling of sweetness; p. 43: especially weak, slightly positive, strong, especially strong, bad taste, normal, slightly good taste, relatively good taste) lack definition or repeatable

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objective results. The Specification recites the property of light feeling in the mouth on a five point scale. The scale includes especially weak, slightly positive, strong, especially strong, and too strong (p. 39-40). However, the Specification fails to indicate any reference to qualify the relative comparisons on the scale. Furthermore, the Specification fails to explain the difference between any of the levels. For example, what is the difference between especially weak and slightly positive (Specification, p. 39, Sensory testing)? The same rationale applies to each of the sensory results.

Finally, examiner notes to establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. MPEP 716.02 (d) II. In the present case, the specification fails to demonstrate criticality in the claimed range. Examples 1-(1), 1-(2), and 1-(3) (specification, p. 40) have ranges of menthol and cool feeling substances outside the presently claimed range. Examples 1-(4), 1-(5), and 1-(6) have ranges within the presently claimed range. However, the differences between the reported sensory perceptions do not appear to establish criticality to the presently claimed range. The specification reports the differences between the measured sensory properties (p. 40, Table 3) from outside the claimed range (ex 1-(1) to 1-(3)) and from within the claimed range (ex 1-(4) to (6)) is "weakly continuous" to "very strongly continuous". As discussed above, the "continuous" feeling lacks an objective standard. Furthermore, the results indicate sensory perception increases as the amount of menthol and cool feeling substances increase.

Applicant argues the sensory tests in the specification are objective because they are based on a large sample size (Remarks, p. 13, top para). Examiner notes the sample size is ten (Remarks, p. 12, 1<sup>st</sup> full para last sentence). Applicant provided no evidence that a sample size of ten represents a statistically large or representative sample size. The argument of counsel cannot take place of evidence on the record.

Applicant argues the taste lasts after storage for 20 days (p. 12, 1<sup>st</sup> full para). Examiner is not persuaded by this argument. The applicant has not demonstrated this is an unexpected result. The results from the storage test were only conducted on example 2. However, example 2 is lemon juice (specification, p. 42). The results are not commensurate in scope with the claims. Furthermore, applicant has not demonstrated the result is unexpected and unobvious and of both statistical and practical significance.

Furthermore, the examiner notes that the specification clearly states the amount of refreshing and cool feeling components are in a range from 0.00005 to 0.05% has a light feeling, sufficient continuation, no heavy taste, good flavor, and taste (specification, p. 41, 1<sup>st</sup> full para).

Applicant argues there is sufficient support for the claimed cool feeling substances (Remarks, p. 13, 1<sup>st</sup> para). Examiner agrees. However, “support” in a 35 USC 112 first paragraph sense is not the issue. The issue is demonstration of unexpected results. As discussed above, Applicant has the burden to establish the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. MPEP 716.02(b).

Applicant argues new claims 25-28 directed to specific examples in the specification have unexpected superior sensory evaluation results (Remarks, p. 13, 2<sup>nd</sup> to last para). Examiner is not persuaded by this argument for the reasons given above. The applicant has not demonstrated the results are unexpected and unobvious and of both statistical and practical significance. The claims are not commensurate in scope with the examples.

In summary, the evidence disclosed within the specification fails to establish the unexpected results in the claimed invention. The applicant has not demonstrated the results are in fact unexpected and unobvious and of both statistical and practical significance. The claims are not commensurate in scope with the results in the specification.

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WALTER MOORE whose telephone number is (571)270-7372. The examiner can normally be reached on Monday-Thursday 9:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Humera Sheikh can be reached on (571) 272-0604. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/WM/ Walter Moore,  
Examiner AU 1789

/C. Sayala/  
Primary Examiner, Art Unit 1781